

REMARKS

Claim Rejection 35 USC §112

Claim 24 has been rejected under 35 USC §112 per the Office Action for not setting forth any steps involved in the method/process. Applicant has amended claim 24 to provide a step so as to clearly determine what process the Applicant is intending to encompass. As such, Applicant respectfully requests that the rejection under 35 USC §112 be removed.

Claim Rejection 35 USC §103

Claims 1-2 and 4-25 are rejected under 35 USC §103 as being unpatentable over Gombotz. Based on the below argument and the amendments to the claims, Applicant believes that the rejection should be removed and the application be allowed to issue.

Prior to listing the differences between the above-captioned application and Gombotz, it would be helpful to discuss what Gombotz does and does not teach. Gombotz discloses a tightly controlled method for making regularly shaped microspheres which are “spherical in shape, without irregularities” (Page 10, Lines 3-4). Gombotz also describes how it is important to produce regular spheres which are not aggregated on Page 8, Lines 16-19. As follows, Gombotz is able to produce these spheres without irregularities by using a complicated procedure involving the

extraction of one or more liquids from a polymer containing structure into another liquid (Page 4, Lines 6-26 and Page 6 Line 20-page 7 Line 26). A necessary component of the spheres is a polymer which forms the structure of the resultant harden microsphere. (Page 4, Lines 24-26).

Generally, the reference provides two methods for forming the microspheres. The first method includes an atomized polymer-containing material which is frozen by a liquefied gas, the liquefied gas is subsequently removed, and the solvent in the polymer-containing particle is subsequently extracted by a further liquid (the non-solvent). This is described in Example 1 of Gombotz. In the second method, atomized polymer-containing particles are frozen in a cold “non-solvent” without needing to use a liquefied gas. In both methods of Gombotz, the polymer-containing particles undergo extraction so that the solvent within them is removed by one or more “non-solvents.”

There are major concepts to note from Gombotz. First, a polymer is necessitated for the formation of the spheres. Along with this, is the fact that Gombotz cannot include active agent above 50%. Additionally, Gombotz is focused intently on creating microspheres, not fractures, as where as previously method the reference clearly states “the microspheres made by this technique are spherical in shape, without irregularities.”

Nowhere within Gombotz is any discussion or even mere suggestion of expansion. There is no component in the microspheres of Gombotz that expands in any way. The word “expand” and variations thereof are notably absent from the reference. Similarly, there is no discussion whatsoever of expansion agents.

In the same vein, nowhere is fracturing of particles discussed as fracturing is mutually exclusive from the spheres created by Gombotz. One could not form perfect microspheres and have expansion, let alone fracturing. In contrast to the current claims of the above-captioned application, the invention relates to a method wherein hollow microporous particles are made in such a manner that an agent expands during the process so as to increase the volume of the material and create fractures therein, thereby enabling the hollow porous fractured material to be formed. This is considered a much more violent and effective method than Gombotz, and has further advantages in that it does not require a complex procedure, and furthermore allows the preparation of materials wherein active ingredient forms all or the majority of the final product.

While the Office action does argue that Gombotz does disclose certain agents which are used as expansion agents in the present application, it is absolutely clear that Gombotz does not disclose all the method steps of the present claims and furthermore does not use the agents as expansion agents at all.

Finally, the products produced in Gombotz are extremely different from those created by the invention of the above-captioned application. In particular, Gombotz requires polymer for the formulation of hardened microspheres and such material would not have the same inherent properties of the invention of the above-captioned application wherein polymer is not required. As such, the microspheres of Gombotz and the fractured particles of the present invention have different compositions, and would have different effects.

Furthermore, Gombotz does not even hint at the mechanism of action of using expansion to create fractures and form the structures of the hollow microporous product of the present invention. No where within Gombotz is fracturing discussed, and instead rather describes how liquid leaves through solvent extraction, a method completely counter and unworkable with the invention of the above-captioned application as in the invention of the above-captioned application, the escaping of the expansion agent is one way in which the fractured porous structure is created.

Due to these extreme differences, and taken in conjunction with the amended claims of the present invention, Applicant respectfully asks for the rejection under 35 USC §103 to be removed.

Respectfully submitted,

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